K012924

JAN 3 0 2002

Datex-Ohmeda
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Summary of Safety and Effectiveness

August 30, 2001

Subject:	510(k) Summary of Safety and Effectiveness Information for the Datex-Ohmeda Tec 7 Anesthesia Vaporizer
Proprietary:	Datex-Ohmeda Tec 7 Anesthesia Vaporizer
Common:	Vaporizer, Anesthesia
Classification:	Anesthesiology, 73CAD, 21CFR868.5880, Class II

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The Datex-Ohmeda Tec 7 Anesthesia Vaporizer is substantially equivalent to the currently marketed Datex-Ohmeda Tec 5 anesthesia Vaporizer, which was the subject of 510(k)s K942091 and K892057.

The Datex-Ohmeda Tec 7 vaporizer is designed for the metered delivery of specific inhalation anesthetic agents for use in continuous flow techniques of inhalation anesthesia. It is available in halothane, isoflurane and sevoflurane variants. Each vaporizer is agent specific and is clearly labeled with the name of the anesthetic agent that it is designed for. The vaporizer is temperature, flow and pressure compensated so that its output remains relatively constant despite cooling due to evaporation, variations in inlet flow and fluctuating pressures. The vaporizer is designed to be used on Selectatec series mounted manifolds.

The Datex-Ohmeda Tec 7 Anesthesia Vaporizer was designed to comply with the applicable portions of the following voluntary standards;

1. EN 740 - Anesthetic Work Stations
2. ISO 5358 - Anesthetic Gas Machines
3. ASTM F1161 - Specifications for Anesthetic Gas Machines

The Datex-Ohmeda Tec 7 Anesthesia Vaporizer and the currently marketed Tec 5 are substantially equivalent in uses, design concepts, technologies and materials. The Datex-Ohmeda Tec 7 Anesthesia Vaporizers have been validated through testing that, in part, support the compliance of the current and predicate device to the above mentioned standards.

Contact: Bill Exner
Vice President, Quality Assurance and Regulatory Affairs

Datex-Ohmeda

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Device Name

Device Name: Proprietary	Datex-Ohmeda Tec 7 Anesthesia Vaporizer
Device Name: Common	Anesthesia Vaporizer
Device Name: Classification	Vaporizer, Anesthesia, Non-heated

Device Classification and Panel

Device Classification:	73CAD – 21CFR868.5880 – Class II
Device Panel:	Anesthesiology

Predicate Devices

Datex-Ohmeda Tec 5 Anesthesia Vaporizer:
510(k) K942091 and 510(k) 892057

Performance Standards Information

To the best knowledge of Datex-Ohmeda, performance standards have not been promulgated by the FDA for this device.

Device Manufacturing Facility Information

Datex-Ohmeda, Inc.
Anesthesia, Drug Delivery and Ventilation Business Unit
Ohmeda Drive
P.O. Box 7550
Madison, WI 53707-7550
608-221-1551 telephone
608-223-2496 facsimile

Establishment Registration and Owner/Operator Numbers

Establishment Registration Number: 2112667
Owner/Operator Number 8030853

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2002

Mr. Bill Exner
Datex-Ohmeda, Inc.
Anesthesia and Drug Delivery Business Unit
P.O. Box 7550
Madison, WI 53707-7550

Re: K012924
Datex-Ohmeda Tec 7 Anesthesia Vaporizer
Regulation Number: 868.5880
Regulation Name: Vaporizer, Anesthesia, Non-heated
Regulatory Class: Class II (two)
Product Code: 73 CAD
Dated: January 2, 2002
Received: January 3, 2002

Dear Mr. Exner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

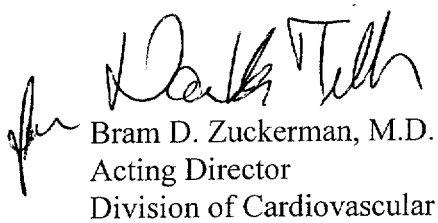
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012924

Device Name: Datex-Ohmeda Tec 7 Anesthesia Vaporizer

Indications For Use:

The Datex-Ohmeda Tec 7 vaporizer is designed for the metered delivery of specific inhalation anesthetic agents for use in continuous flow techniques of inhalation anesthesia. It is available in halothane, isoflurane and sevoflurane variants. Each vaporizer is agent specific and is clearly labeled with the name of the anesthetic agent that it is designed for. The vaporizer is temperature, flow and pressure compensated so that its output remains relatively constant despite cooling due to evaporation, variations in inlet flow and fluctuating pressures. The vaporizer is designed to be used on Selectatec series mounted manifolds.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and
Neurological Devices

510(k) Number: K012924

Prescription Use ✓ OR Over-The-Counter Use
(Per 21CFR801.109) (Optional Format 1-2-96)